

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**UNITED STATES OF AMERICA, *et al.*, *ex*
rel. JESSICA PENELOW and CHRISTINE
BRANCACCIO,**

Plaintiffs,

v.

JANSSEN PRODUCTS, LP,

Defendant.

Civil Action No. 12-7758 (ZNQ) (JBD)

OPINION

QURAISHI, District Judge

This matter comes before the Court upon Defendant Janssen Products, LP's ("Janssen") Motion to Strike the testimony of Israel Shaked ("Shaked") and Ian Dew ("Dew") pursuant to Federal Rule of Evidence 702 ("Rule 702"), (the "Motion", ECF No. 402). Janssen filed a Brief in Support of the Motion, ("Moving Br.", ECF No. 402-1) and Relators Jessica Penelow and Christine Brancaccio (collectively, "Relators") filed a Brief in Opposition ("Opp'n Br.", ECF No. 408). Janssen has not filed a Reply.

The Court has carefully considered the parties' submissions and decides the matter without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the reasons set forth below, the Court will **DENY** Janssen's Motion.

I. BACKGROUND & PROCEDURAL HISTORY

The factual background of this matter is set forth in detail in *United States ex rel. Penelow v. Janssen Products, LP*, Civ No. 12-7758, 2021 WL 6052425 (D.N.J. Dec. 21, 2021). Briefly, in

2012, Relators¹ filed an action on behalf of the federal government, twenty-six states, and the District of Columbia alleging fifty-six counts under the Federal False Claims Act (“FCA”), the Federal Anti-Kickback Statute (“AKS”), and the false claims acts of various states. *Id.* at *1. The claims in this action arise from Janssen’s purported kickback scheme and off-label (“OL”) promotion of two HIV/AIDS drugs: Prezista and Intelence. *Id.*

On December 21, 2021, the Court denied Janssen’s motion for summary judgment and allowed the FCA and AKS claims to proceed. *Id.* at *7–11. On January 10, 2022, the Court considered several motions by both parties to exclude expert opinion and testimony, including Janssen’s first challenge of Shaked and Dew, Relators’ damages experts, in a *Daubert* motion. *United States ex rel. Penelow v. Janssen Products, LP*, Civ No. 12-7758, 2022 WL 94535, at *14–15 (D.N.J. Jan. 10, 2022). Shaked’s proposed testimony concerned the relationship between Janssen’s OL marketing scheme and prescription rates and the total damages related to Janssen’s alleged FCA and AKS violations. *Id.* In reaching his conclusions, Shaked conducted multiple statistical analyses and relied on Dew, a consultant, to assist him in gathering the necessary data. *Id.* at *14.

In its *Daubert* motion, Defendant challenged the reliability of Shaked’s opinions, and by proxy, of Dew’s opinions. *Id.* at *15. The Court denied Defendant’s *Daubert* motion as to these witnesses and permitted Shaked to testify at trial. *Id.* at *15–16. First, the Court found that Shaked used a reliable methodology with “good grounds” to reach his opinion on causation regarding OL promotion and prescription rates. *Id.* at *16. Since Shaked used data pertinent to the facts of the

¹ Between 2006 and 2013, Relator Jessica Penelow worked as a sales consultant for Tibotec Therapeutics, a subsidiary of Johnson & Johnson that became known as Janssen in 2011. (“Second Am. Compl.” ¶ 47, ECF No. 90.) While working for Tibotec, she marketed several HIV drugs, including Prezista and Intelence, to doctors in Manhattan. (*Id.*) Similarly, in 2006, Relator Christine Brancaccio started working for Janssen as a sales representative and marketed Prezista and Intelence to providers in Long Island and Queens. (*Id.* ¶ 49.)

case, the Court additionally found that his analysis was relevant. *Id.* The Court further explained that the proper venue for challenges to Shaked's assumptions and choice of methodology is at trial during cross-examination. *Id.*

In May 2024, the Court presided over a 24-day trial. Amid trial, following Shaked's testimony but before the jury's verdict was entered, Janssen filed its Motion. The Court did not immediately rule on the Motion but held it under advisement until after trial. On June 13, 2024, the jury returned its verdict, finding that Janssen violated the Federal FCA and the FCA of twenty-six states by unlawfully promoting Prezista and Intelence and considered Janssen liable for \$150,005,920 in damages. The Court entered judgment and Janssen's Motion remained pending.

II. LEGAL STANDARD

Rule 702 governs the admissibility of expert testimony and provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods;
and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. "Rule 702 embodies three distinct substantive restrictions on the admission of expert testimony: qualification, reliability, and fit." *Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 80 (3d Cir. 2017) (quoting *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000)).

To satisfy the qualification requirement, an expert must possess “specialized knowledge regarding the area of testimony.” *Betterbox Comm’ns Ltd. v. BB Techs., Inc.*, 300 F.3d 325, 327 (3d Cir. 2002) (quotation marks and citation omitted). “The basis of this specialized knowledge can be practical experience as well as academic training and credentials.” *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998) (quotation marks and citations omitted). The qualification requirement is interpreted “liberally,” *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008), and “a broad range of knowledge, skills, and training qualify an expert as such.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994) (citation omitted).

To be reliable, the purported expert’s testimony “must be based on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation’; the expert must have ‘good grounds’ for his [or] her belief.” *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003) (citation omitted). Finally, to satisfy the “fit” requirement, “the expert’s testimony must be relevant for the purposes of the case and must assist the trier of fact.” *Id.* “Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993) (citation omitted). “Rule 702’s ‘helpfulness’ standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.” *Id.* at 591–92.

Rule 702 “has a liberal policy of admissibility.” *Kannankeril v. Terminix Int’l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997) (citation omitted). “If the expert meets [these] liberal minimum qualifications, then the level of the expert’s expertise goes to credibility and weight, not admissibility.” *Id.* at 809.

III. DISCUSSION

The Court previously held that Shaked’s analyses were admissible because “[m]any of Janssen’s arguments attack Shaked’s assumptions and question his choice of methodology: the proper venue for such arguments is at trial during cross-examination.” *United States ex rel. Penelow*, 2022 WL 94535, at * 16. Shaked’s general theory of causation and damages was to look at the relationships between payments to speakers, effects of payments on prescribing physicians, and the relationship between speakers and non-speakers. *Id.* From these analyses, Shaked deduced that: there was a “positive relationship between compensation paid to physicians and subsequent prescriptions written for Prezista and Intelence”; Janssen’s conduct “influenced OL prescriptions that were then reimbursed by the government for the relevant periods”; and the total number of damages related to Janssen’s alleged violations of the FCA and AKS. *Id.*

In the instant action, Janssen again challenges the factual assumptions underlying Shaked’s opinions. Specifically, Janssen argues that Shaked’s analysis is dependent on erroneously assuming that (1) every single sales call and speaker event contained an OL message for both Prezista and Intelence; (2) every instance of OL messaging effectively “influenced” doctors in writing prescriptions; and (3) exposure to alleged OL messaging or receipt of a speaker fee tainted all subsequent prescriptions. (Moving Br. at 5–9.) Relators frame Janssen’s Motion as challenging (1) Shaked’s definition of an “influenced” physician; (2) Shaked’s analyses showing a correlation between OL messaging and/or payments to speakers; and (3) Shaked’s methods for determining damages. (Opp’n Br. at 1.) For the reasons stated below, and in the Court’s prior opinion on this issue, the Court will deny Janssen’s Motion.

First, Janssen argues that Shaked’s definition of an “influenced” physician, which Shaked used to assess causation and damages, relied on the assumption that every sales call and speaker

event contained an OL message for both Prezista and Intelence and that, during certain periods of time, all four of Janssen's OL messages for these drugs were presented at every sales call and speaker event. (Moving Br. at 5.) Janssen points to certain trial testimony that allegedly undermines Shaked's methodology. (*Id.* at 5–6.) Relators argue that Shaked's definition of an "influenced" physician, i.e., "a doctor who was subject to a Janssen sales call, was a paid speaker, or was an attendee at a speaker event" is based on good grounds and supported by the trial testimony of several sales representatives. (*Id.* at 3.)

According to Shaked, an "influenced" doctor is simply one who was exposed to Janssen's OL marketing campaign in some form. (Opp'n Br. at 5.) This definition assumes, based on the evidence, that at least one OL message was delivered during the first point of contact and that additional OL messages were delivered over time. (*Id.* at 6.) Relators claim that it was reasonable for Shaked "to assume that a Janssen sales representative delivered the relevant OL messages to each [i]nfluenced doctor within his or her territory during the multiple points of influence over the 9-year relevant period here." (*Id.* at 8.)

The Court agrees with Relators that Shaked's definition of an influenced physician is based on reasonable assumptions and is unpersuaded by Janssen's argument that certain trial testimony undermined Shaked's methodology. Janssen largely cherry-picks trial testimony that is taken out of context but, as Relators highlight, the trial featured significant testimony of several sales representatives whom all attested that Janssen's OL promotion was widespread and reached physician's simultaneously through sales calls and speaker events. (*Id.* at 9–11) (citing testimony).

Secondly, Janssen argues that Shaked incorrectly assumed that every instance of OL messaging "influenced" a prescription. (Moving Br. at 8.) Relators contend that Shaked did not make such an assumption. (Opp'n Br. at 13.) Instead, Relators contend that Shaked analyzed the

OL prescription rates of influenced physicians in comparison to those of non-influenced physicians as well as rates of paid speakers and non-speakers. (*Id.*) Shaked then opined that there is a strong correlation between Janssen's OL marketing and the high rates of Prezista and Intelence prescriptions by influenced physicians. (*Id.*)

As Relators note, the Court already addressed this causation argument in its prior opinion on Janssen's *Daubert* motion. There, the Court explained that it "reviewed Shaked's report to determine whether he used methods with good grounds to reach his general causation opinions." *United States ex rel. Penelow*, 2022 WL 94535, at *16. The Court then considered Shaked's statistical methods. As the Court explained in its prior opinion,

[t]he Difference of Two Population Means Test (the two-factor correlation analysis Janssen references) determines whether there is a statistically significant difference between two independent population means. (Shaked Report at 73.) If the z-score is higher than the critical value, then there is a statistically significant difference between the two populations. (*Id.*) Here, Shaked clearly explains his rationale for setting up tests, tests each of his hypotheses (*e.g.*, whether payments "influenced" physicians) against the negative hypotheses (*e.g.*, whether payments did not "influence" physicians), and used z-scores to determine whether the results were statistically significant. (Shaked Report ¶¶ 76, 96, 105, 131, 140.) Moreover, Shaked calculated the Spearman Rank Correlation values for dollar amounts paid to speakers and their dollar amount of prescriptions. (*Id.* at 36.) As understood by the Court and expressed by Shaked, the Spearman Correlation Test measures the positive relationship between two variables; a value of "-1" implies a weak association, a value of "0" implies no association, and a value of "1" implies a positive association. (*Id.* at 73–74.) The Spearman Rank Correlation Significance Test analyzes the strength of the correlation test and the possibility that the correlation is by chance. (*Id.* at 74.) Furthermore, contrary to Janssen's argument that Shaked did not run regressions, Shaked ran multiple regressions on the data when challenged by Anupam Jena; however, Shaked chose not to include it in the supplemental report because he believed that the identical results did not need to be included in his report. (Chuderewicz Decl., Ex B., "Shaked Dep." 291:10–25, ECF No. 202-4.) With positive values, high z-scores, and high t-values, the values are statistically significant (*i.e.*, cannot be rejected) under

accepted statistical checks.² (Shaked Report at 74.) As such, the Court finds that Shaked’s report has “good grounds” and is, therefore, reliable.

(*Id.*) At trial, Shaked testified to the same approved methodology, analyses conducted, and conclusions reached.

Given that courts have allowed experts to opine as to the causal link between pharmaceutical OL marketing efforts and doctors’ prescribing decisions, and that Relators elicited testimony from several sales representatives at trial who say they witnessed the OL marketing scheme’s impact on prescription rates, (Opp’n Br. at 14.) (citing testimony), the Court rejects Janssen’s challenge to Shaked’s correlation testimony. *See, e.g., Smith v. Pfizer Inc.*, 714 F. Supp. 2d 845, 856 (M.D. Tenn. 2010); *United States ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1039–40 (C.D. Cal. 2016); *Hanrahan v. Wyeth, Inc.*, Civ. No. 04-1255, 2012 WL 2395986, at *5 (E.D. Mo. June 25, 2012).

Finally, Janssen argues that Shaked’s method of calculating damages is flawed because he attributed a patient’s lifelong OL Prezista and Intelence prescriptions to the influenced physician who first prescribed the medication. (Moving Br. at 9.) Although a damages expert may not rely on assumptions wholly without evidence in the record, *Elcock*, 233 F.3d at 738, that is not what happened here. Shaked (and Dew)

determined the first time each influenced doctor prescribed Prezista and Intelence, they then identified the date of the first sales call or speaking event associated with each prescriber, they quantified the number of sales calls and speaking events for each prescriber, and they quantified total speaking events and fees paid for each speaker. They further determined the average number of contacts per doctor

² When applying the Rank Correlation Significance Test, Shaked calculated a correlation of 0.235 and a t-value of 4.212 for the correlation between a change in total compensation and average annual prescription; he also calculated a correlation of 0.406 and a t-value of 31.944 for the correlation between a change in marketing contacts and OL prescriptions. (Shaked Report ¶¶ 89, 119.) According to the t-score table found, the t-values for 99.995% confidence in the result is 3.97 for a data set of 200 values and 3.92 for a data set of 500 values. <https://faculty.washington.edu/heagerty/Books/Biostatistics/TABLES/t-Tables/>. As such, the Court finds that the values calculated are reliable.

and confirmed that doctors were called upon by Janssen multiple times.

(Opp’n Br. at 16.) Evidently, Shaked based his assumptions on data pertinent to the facts of the case.

In sum, an expert may make an assumption of fact “so long as such assumptions have a reasonable basis in the available record.” *Brill v. Marandola*, 540 F. Supp. 2d 563, 568 (W.D. Pa. 2008). Here, the Court finds once again that Shaked has a basis for his assumptions and definitions for his damages and causation analyses. These assumptions are reasonably sufficient to pass muster under *Daubert*. *Elcock*, 233 F.3d at 755; *Paoli*, 35 F.3d at 744 (3d Cir. 1994) (“The evidentiary requirement of reliability is lower than the merits standard of correctness.”). Accordingly, striking Shaked and Dew’s testimony is not warranted, and Janssen’s Motion will be denied. *Elcock*, 233 F.3d 734 at 755 (explaining that expert reports do not warrant exclusion merely for relying on assumptions—they only warrant exclusion where such assumptions lack evidence or are wholly unreasonable); *see also Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002) (“A party confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts and assumptions as the basis for his opinion can highlight those weaknesses through effective cross-examination.”).

IV. CONCLUSION

For the foregoing, the Court will **DENY** Janssen’s Motion to Strike the testimony of Shaked and Dew. An appropriate order will follow.

Dated: January 30, 2025

s/ Zahid N. Quraishi

ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE